**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**[FWS–HQ–FAC–2021–N167; FXFR13110900000 201 FF09F11000; OMB Control Number 1018–New]**

# Agency Information Collection Activities; Administration of U.S. Fish and Wildlife Service Investigational New Animal Drug (INAD) Program

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection in use without Office of Management and Budget (OMB) approval.

**DATES:** Interested persons are invited to submit comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

**ADDRESSES:** Send your comments on the information collection request (ICR) by mail to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to Info_Coll@fws.gov. Please reference OMB Control Number "1018–INAD" in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new,

proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that

your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Abstract:* The Aquatic Animal Drug Approval Partnership (AADAP) Program is part of the Fish and Aquatic Conservation fish health network. It is the only program in the United States singularly dedicated to obtaining U. S. Food and Drug Administration (FDA) approval of new medications needed for use in fish culture and fisheries management. Ultimately, the AADAP program allows fisheries professionals to more effectively and efficiently rear and manage a variety of fish species to meet production goals, stock healthy fish, and maintain a healthy environment. In order for participants (U.S. aquaculture facilities or researchers) to be able to use an unapproved drug under AADAP's National Investigational New Animal Drug (INAD) Program, they need to follow the FDA-approved study protocol(s) and submit the required data forms, including the INAD treatment data, to AADAP's INAD Program.

There are 18 approved INADs approved for use within the Service's INAD Program (see fws.gov/fisheries/aadap/inads.html) described as follows:

**Medicated Feeds**

**Florfenicol (Aquaflor®) INAD #10–697** – Aquaflor® is an aquaculture premix containing florfenicol and is only available through Merck Animal Health. The primary goal of field studies conducted under INAD #10–697 is to evaluate the efficacy of florfenicol-medicated feed for controlling mortality in a variety of fish species diagnosed with a variety of diseases that are caused by pathogens susceptible to florfenicol.

**Slice® (Emamectin Benzoate) INAD #11–370** – SLICE® is an aquaculture premix containing emamectin benzoate and is only available through Merck Animal

Health. SLICE® premix can be purchased through Merck Animal Health and sent to an aquaculture feed mill for top coating. The primary goal of field studies conducted under INAD #11–370 is to evaluate the efficacy of SLICE®-medicated feed and safety of SLICE® to control mortality caused by external parasites in a variety of freshwater and marine fish species.

**Oxytetracylcine dihydrate (Terramycin® 200 for Fish) INAD #9332** – Terramycin 200® for fish is an aquaculture premix containing oxytetracycline dehydrate (OTC) and is available through Syndel USA. Feed medicated with OTC can be purchased from aquaculture feed mills and used to treat bacterial diseases or to apply a skeletal mark on the fish. The primary goal of field studies conducted under INAD #9332 is to generate additional OTC-medicated feed efficacy data which can be used to expand the existing OTC label claims. Five treatment options are allowed, and disposition of investigational animals (including withdrawal times) vary with treatment regimen.

**17α–methyltestosterone INAD #11–236** – 17α-methyltestosterone (MET) is an aquaculture premix and is only available through Rangen Inc. The primary goal of studies conducted under INAD #11–236 is to generate data evaluating the efficacy of MET administered in feed to larval tilapia to produce populations comprised of >90% male fish.

**17α–methyltestosterone INAD #8557** – 17α-methyltestosterone (MET) is an aquaculture premix and is only available through Rangen Inc. The primary goal of studies conducted under INAD #8557 is to generate data evaluating the efficacy of MET administered in feed to larval rainbow trout and Atlantic salmon to produce masculinized female fish that produce sperm.

**17β–Estradiol INAD #12–671** – 17β-estradiol (E2) will be administered as a medicated feed and is only available to FDA-approved facilities. The primary goal of studies conducted under INAD #12–671 is to generate data evaluating the efficacy

of E2 administered in feed to larval brook trout to produce feminized male fish that produce eggs.

**Immersion**

**Chloramine–T INAD #9321** – Chloramine–T (CLT) is a powder that is applied as an immersion bath treatment. CLT is only available for purchase through Syndel USA or B.L. Mitchell, Inc. The primary goal of field studies conducted under INAD #9321 is to evaluate the efficacy of CLT for controlling mortality in a variety of freshwater fish species for bacterial diseases not currently listed on the approved label. Approval of INAD #9321 is for non-labeled use only and its use must comply with the approved label directions.

**Hydrogen peroxide (35% Perox Aid®) INAD #11–669** – 35% Perox-Aid® ($H_2O_2$) is a liquid solution containing hydrogen peroxide that is applied as an immersion bath treatment. $H_2O_2$ is only available for purchase through Syndel USA. The primary goal of field studies conducted under INAD #11–669 is to evaluate the efficacy of $H_2O_2$ for controlling mortality caused by specific ectoparasites in freshwater or marine finfish species. It is also expected that the additional data will be used to expand the current $H_2O_2$ label claim. Approval of INAD #11–669 is for non-labeled use only and its use must comply with the approved label directions.

**Oxytetracycline hydrochloride INAD #9033** – Oxytetracycline hydrochloride (OTIMM) is an aquaculture premix containing oxytetracycline hydrochloride and is available through Pharmgate. OTIMM is available for purchase through many local farm and ranch stores or veterinarian supply outlets. The primary goal of field studies conducted under INAD #9033 is to evaluate the efficacy of OTIMM for controlling mortality in a variety of freshwater and marine finfish species for bacterial diseases. Immersion therapy is often the only option when treating young fish not yet accustomed to feeding on man-made fish diets.

**Diquat® INAD #10–969** – Reward® (DQT) is a liquid concentrate containing diquat dibromide that is applied as an immersion bath treatment. DQT is available for purchase through many local farm and ranch stores or through Syngenta Crop Protection, LLC. The primary goal of field studies conducted under INAD #10-969 is to evaluate the efficacy of DQT for controlling mortality in all freshwater-reared finfish diagnosed with BGD or external flavobacteriosis.

**Sedatives**

**AQUI-S®20E INAD #11–741** – Aqui-S®20E is a liquid containing 10% eugenol that is applied as an immersion bath treatment. Aqui-S®20E is only available for purchase through AquaTactics Fish Health. The primary goal of field studies conducted under INAD #11–741 is to evaluate the efficacy of Aqui-S®20E for use as an anesthetic/sedative in all freshwater-reared finfish, freshwater prawn, all saltwater-reared finfish, and sharks.

**Spawning Aids**

**Lutenizing Hormone – Releasing Hormone (LHRHa) INAD #8061** – Luteinizing Hormone – Releasing Hormone analogue (LHRHa) is a solution that is applied as either an intraperitoneal (IP) or intramuscular (IM) injection. LHRHa is only available for purchase through Syndel USA. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #8061 is to generate data to help determine appropriate LHRHa treatment regimens for inducing gamete maturation in a variety of cultured and wildstock finfish species.

**GnRH IIa Chicken Gonadotropin – Releasing Hormone II analog INAD #13–345** – GnRH IIa is a synthetic peptide analogue of chicken gonadotropin-releasing hormone (cGnRH IIa). It is presented as a dry powder to be resuspended in saline solution for IP injection and is only available for purchase through

AquaTactics Fish Health. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #13–345 is to generate data to help determine appropriate GnRH IIa treatment regimens for use as a spawning aid for female ictalurids.

**Ovaplant® Salmon Gonadotropin – Releasing Hormone analoque (sGnRHa) INAD #11–375** – Ovaplant® is a synthetic peptide analogue of salmon gonadotropin-releasing hormone (sGnRHa). It is presented in a biodegradable cholesterol-based matrix as an IM pellet implant and is only available for purchase through Syndel USA. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #11–375 is to generate data to help determine appropriate Ovaplant® treatment regimens.

**Ovaplant®–L Salmon Gonadotropin – Releasing Hormone analoque (sGnRHa) INAD #13–298** – Ovaplant®–L is a synthetic peptide analogue of salmon gonadotropin-releasing hormone (sGnRHa). It is presented in a sustained release gel for injection and is only available for purchase through Syndel USA. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #13–298 is to generate data to help determine appropriate Ovaplant-L treatment regimens for inducing gamete maturation in a variety of cultured finfish species.

**Common Carp Pituitary (CCP) INAD #8391** – Common carp pituitary (CCP) is a powder (for suspension) that is applied as either an IP or IM injection. CCP is only available for purchase through Argent Aquaculture. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need

hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #8391 is to generate data to help determine appropriate CCP treatment regimens for inducing gamete maturation in a variety of cultured and wildstock finfish species.

**Marking**

**Calcein (Se–Mark®) INAD #10–987** – Calcein (Se-Mark®) is a liquid that contains 1% calcein for bath marking treatments on finfish and select freshwater mussels. Calcein is only available for purchase through Syndel USA. Calcein is a fluorochrome compound that chemically binds with alkaline earth metals such as calcium, and upon binding, shows a marked increase in fluorescence when excited with blue light of about 500 nm wavelength. The primary goal of field studies conducted under INAD #10–987 is to establish the effectiveness of calcein to mark fin rays, scales, otoliths, and other calcified fish, oysters, or selected mussel tissues via immersion baths. This is a non-lethal marking evaluation method.

**Injectable**

**Erythromycin 200 Injectable INAD #12–781** – Erymicin 200 Injection (Erymicin 200) is a solution that contains erythromycin for injection on juvenile and adult Salmonids. Erymicin 200 is only available for purchase through Syndel USA. The primary goal of field studies conducted under INAD #12–781 is to evaluate the efficacy of erythromycin for 1) controlling mortality caused by BKD (causative agent: *Renibacterium salmoninarum*) in salmonid species; and 2) control the vertical transmission of *R. salmoninarum* from BKD positive female broodstock to eggs/progeny.

Approved INAD study protocols require submission of the following forms associated with the data collection:

- Form–W: Worksheet (all INADs);
- Form–1: Report on Receipt of Drug (all INADs);

- Form–2A or 2B:  Chemical Use Log (all INADs);
- Form–3:  Diagnosis, Treatment, and Mortality/Spawning/Anesthetic Record (all INADs);
- Form–4: Necropsy Report Form (specific INADs);
- Form–4a Report on Efficacy Determination Sample (specific INADs); and,
- Form–5: Transfer of Treated Fingerling (specific INADs).

The INAD forms listed above collect the following information from program participants (specific information may vary depending on INAD protocol used):

- Study identification number and title;
- Sponsor name and contact information;
- Facility name;
- Study director and contact information;
- Principal clinical field trial coordinator name;
- Study monitor’s name and addresses;
- Investigator’s name and addresses;
- Proposed study starting and completion dates;
- Background, purpose, and objectives of study;
- Study materials;
- Experimental units;
- Entrance criteria;
- Identification of treatment groups;
- Treatment schedules;
- Treatment response parameters;
- Recordkeeping procedures;
- Disposition of investigational animals;
- Disposition of investigational drug;
- Data handling, quality control, monitoring, and administrative

responsibilities;

- Plans for data analysis;
- Protocol and protocol amendments; and,
- Protocol deviations.

The Service's AADAP Program will use the information that is collected on the study forms to ensure the studies are following the guidelines set by the FDA. The study data will be downloaded to a spreadsheet where it will be analyzed for compliance. Summary reports will be created from the data collected from the forms and will be submitted to the FDA, as required. Submission of the data forms is required by the FDA for the facility to participate in the INAD Program.

A cooperative agreement is also needed between the participating companies/agencies and the Service's AADAP Program. This agreement establishes obligations to be met and procedures to be followed by the Service and participant to establish and maintain cooperative INADs to enable the use of certain drugs and chemicals under the INAD process as set forth by the FDA. The goal of this agreement is to consolidate the INAD process; eliminate duplication of effort; reduce workloads and costs; and ensure needed drugs are made available to aquaculture and fisheries management facilities in the U.S. in compliance with FDA regulations.

Additional information for the INAD Program and how to participate can be found at the following link : https://www.fws.gov/fisheries/aadap/inad-university.html. This webpage describes frequently asked questions regarding how to participate in the INAD Program and what is expected of the participants. The site also includes the investigator and monitor guides created to explain the INAD Program process to study participants. We are currently developing additional study templates for the INADs for use as a guide for filling out the forms. These templates will provide study participants with helpful information to correctly complete each form. We also

created a user manual for the online INAD database used to enter the data that also describes each step of the database for the INAD participants.

*Title of Collection:* Administration of U.S. Fish and Wildlife Service Investigational New Animal Drug (INAD) Program.

*OMB Control Number:* 1018–New.

*Form Number(s):* Form–W, Form–1, Form–2A or 2B, Form–3, Form–4, Form–4a, and Form–5.

*Type of Review:* Existing collection in use without an OMB control number.

*Respondents/Affected Public:* Respondents will be the private aquaculture facilities; universities; and State, local, and Tribal governments that have a need to use INADs.

*Respondent's Obligation:* Required to obtain or retain a benefit.

*Frequency of Collection:* One time for the initial registration and submission of cooperative agreement, and on occasion for submission of study data.

*Total Estimated Annual Nonhour Burden Cost:* There is an enrollment fee that is currently $700 per INAD per facility each year as of 2021. The facility is also responsible for purchasing the INAD from the appropriate drug supplier. All equipment that would be used for the INAD studies is typically standard equipment already used by the facilities.

| Requirement | Average Number of Annual Respondents | Average Number of Responses Each | Average Number of Annual Responses* | Average Completion Time per Response (Hours) | Estimated Annual Burden Hours* |
|---|---|---|---|---|---|
| ***Cooperative Agreement*** | | | | | |
| Private Sector | 15 | 1 | 15 | 2 | 30 |
| Government | 5 | 1 | 5 | 2 | 10 |
| ***Medicated Feed – Florfenicol (Aquaflor®) INAD #10–697*** | | | | | |
| Private Sector | 4 | 1 | 4 | 0.25 | 1 |
| Government | 4 | 1 | 4 | 0.25 | 1 |
| ***Medicated Feed – Slice® (Emamectin Benzoate) INAD #11–370*** | | | | | |
| Private Sector | 5 | 1 | 5 | 0.25 | 1 |
| Government | 4 | 1 | 4 | 0.25 | 1 |
| ***Medicated Feed – Oxytetracylcine dihydrate (Terramycin® 200 for Fish) INAD #9332*** | | | | | |
| Private Sector | 5 | 1 | 5 | 0.25 | 1 |
| Government | 16 | 1 | 16 | 0.25 | 4 |
| ***Medicated Feed – 17α–methyltestosterone INAD #11–236*** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Private Sector | 4 | 1 | 4 | 0.25 | 1 |
| Government | 5 | 1 | 5 | 0.25 | 1 |
| ***Medicated Feed – 17α–methyltestosterone INAD #8557*** | | | | | |
| Private Sector | 5 | 1 | 5 | 0.25 | 1 |
| Government | 1 | 1 | 1 | 0.25 | 0 |
| ***Medicated Feed – 17β–Estradiol INAD #12–671*** | | | | | |
| Private Sector | 1 | 1 | 1 | 0.25 | 0 |
| Government | 1 | 1 | 1 | 0.25 | 0 |
| ***Immersion – Chloramine–T INAD #9321*** | | | | | |
| Private Sector | 1 | 1 | 1 | 0.25 | 0 |
| Government | 8 | 1 | 8 | 0.25 | 2 |
| ***Immersion – Hydrogen peroxide (35% Perox Aid®) INAD #11–669*** | | | | | |
| Private Sector | 1 | 5 | 5 | 0.25 | 1 |
| Government | 2 | 2 | 4 | 0.25 | 1 |
| ***Immersion – Oxytetracycline hydrochloride INAD #9033*** | | | | | |
| Private Sector | 1 | 1 | 1 | 0.25 | 0 |
| Government | 2 | 2 | 4 | 0.25 | 1 |
| ***Immersion – Diquat® INAD #10–969*** | | | | | |
| Private Sector | 1 | 1 | 1 | 0.25 | 0 |
| Government | 7 | 2 | 14 | 0.25 | 4 |
| ***Sedative – AQUI–S®20E INAD #11–741*** | | | | | |
| Private Sector | 11 | 1 | 11 | 0.25 | 3 |
| Government | 73 | 1 | 73 | 0.25 | 18 |
| ***Spawning Aid – Lutenizing Hormone – Releasing Hormone (LHRHa) INAD #8061*** | | | | | |
| Private Sector | 19 | 1 | 19 | 0.25 | 5 |
| Government | 7 | 2 | 14 | 0.25 | 4 |
| ***Spawning Aid – GnRH IIa Chicken Gonadotropin – Releasing Hormone II analog INAD #13–345*** | | | | | |
| Private Sector | 9 | 1 | 9 | 0.25 | 2 |
| Government | 1 | 1 | 1 | 0.25 | 0 |
| ***Spawning Aid – Ovaplant® Salmon Gonadotropin – Releasing Hormone analoque (sGnRHa) INAD #11–375*** | | | | | |
| Private Sector | 5 | 1 | 5 | 0.25 | 1 |
| Government | 12 | 1 | 12 | 0.25 | 3 |
| ***Spawning Aid – Ovaplant®-L Salmon Gonadotropin – Releasing Hormone analoque (sGnRHa) INAD #13–298*** | | | | | |
| Private Sector | 1 | 1 | 1 | 0.25 | 0 |
| Government | 4 | 1 | 4 | 0.25 | 1 |
| ***Spawning Aid – Common Carp Pituitary (CCP) INAD #8391*** | | | | | |
| Private Sector | 5 | 1 | 5 | 0.25 | 1 |
| Government | 7 | 2 | 14 | 0.25 | 4 |
| ***Marking – Calcein (Se–Mark®) INAD #10–987*** | | | | | |
| Private Sector | 1 | 1 | 1 | 0.25 | 0 |
| Government | 2 | 1 | 2 | 0.25 | 1 |
| ***Injectable – Erythromycin 200 Injectable INAD #12–781*** | | | | | |
| Private Sector | 2 | 1 | 2 | 0.25 | 1 |
| Government | 14 | 1 | 14 | 0.25 | 4 |
| ***Form–W "Worksheet for Designing Individual Field Trials"*** | | | | | |
| Private Sector | 63 | 3 | 189 | 1 | 189 |
| Government | 148 | 3 | 444 | 1 | 444 |
| ***Form–1, Report on Receipt of Drug*** | | | | | |
| Private Sector | 45 | 2 | 90 | 0.5 | 45 |
| Government | 88 | 2 | 176 | 0.5 | 88 |
| ***Form FFC-2A or 2B, Chemical Use Log*** | | | | | |
| Private Sector | 63 | 3 | 189 | 0.25 | 47 |
| Government | 148 | 3 | 444 | 0.25 | 111 |
| ***Form -3, Diagnosis, Treatment, and Mortality Record*** | | | | | |
| Private Sector | 63 | 3 | 189 | 1.5 | 284 |
| Government | 148 | 3 | 444 | 1.5 | 666 |
| ***Form-4: Necropsy Report Form*** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Private Sector | 27 | 1 | 27 | 0.5 | 14 |
| Government | 24 | 1 | 24 | 0.5 | 12 |
| ***Form-4a Report on Efficacy Determination Sample*** | | | | | |
| Private Sector | 3 | 2 | 6 | 0.75 | 5 |
| Government | 3 | 2 | 6 | 0.75 | 5 |
| ***Form-5: Transfer of Treated Fingerling*** | | | | | |
| Private Sector | 2 | 8 | 16 | 0.5 | 8 |
| Government | 1 | 1 | 1 | 0.5 | 1 |
| ***Totals:*** | *1,097* | | *2,545* | | *2,027* |

*Rounded

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Madonna Baucum,**
*Information Collection Clearance Officer,*
*U.S. Fish and Wildlife Service.*
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